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Review Article

Newborn hearing screening protocols and their outcomes: A systematic review

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ABSTRACT

Objective: To conduct a review of the most current research in objective measures used within newborn hearing screening protocols with the aim of exploring the actual protocols in terms of the types of measures used and their frequency of use within a protocol, as well as their outcomes in terms of sensitivity, specificity, false positives, and false negatives in different countries worldwide.

Methods: A systematic literature review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis. Electronic databases such as PubMed, Google Scholar and Science Direct were used for the literature search. A total of 422 articles were identified, of which only 15 formed part of the current study. The 15 articles that met the study's criteria were reviewed. Pertinent data and findings from the review were tabulated and qualitatively analysed under the following headings: country; objective screening and/or diagnostic measures; details of screening protocol; results (including false positive and negative findings, sensitivity and/or specificity), conclusion and/or recommendations. These tabulated findings were then discussed with conclusions and recommendations offered.

Results: Findings reported in this paper are based on a qualitative rather than a quantitative analysis of the reviewed data. Generally, findings in this review revealed firstly, that there is a lack of uniformity in protocols adopted within newborn hearing screening. Secondly, many of the screening protocols reviewed consist of two or more tiers or stages, with transient evoked otoacoustic emissions (TEOAEs) and automated auditory brainstem response (AABR) being most commonly used. Thirdly, DPOAEs appear to be less commonly used when compared to TEOAEs. Lastly, a question around routine inclusion of AABR as part of the NHS protocol remains inconclusively answered.

Conclusions: There is sufficient evidence to suggest that the inclusion of AABR within a NHS programme is effective in achieving better hearing screening outcomes. The use of AABR in combination with OAEs within a test-battery approach or cross-check principle to screening is appropriate, but the inclusion of AABR to facilitate appropriate referral for diagnostic assessment needs to be systematically studied.

1. Introduction

Early detection of hearing loss is conducted through newborn hearing screening (NHS). Identification of hearing loss through NHS has been investigated for over a century [1]. Investigations that began with the use of subjective evaluation in the form of behavioural responses in the 1800s has progressed to the use of objective measurements in the form of otoacoustic emissions (OAEs) and auditory brainstem response (ABR) [1].

A variety of objective screening measures may be used to conduct hearing screening in the newborn. These include transient evoked otoacoustic emissions (TEOAEs), distortion product otoacoustic emissions (DPOAEs), the automated auditory brainstem response (AABR) or a combination of otoacoustic emissions (OAEs) and AABR [2]. OAEs are acoustic signals generated from the outer hair cells within the cochlea reflecting the mechanical processes that provide an indication of the integrity of the cochlea [3]. Emissions are categorised by the presence or absence of an evoking stimulus with evoked OAEs being of greater clinical significance [4]. The AABR consists of an electrical response to auditory stimuli and assesses the peripheral auditory pathway from the ear to the brainstem [5].

Screening protocols and measures used within NHS programmes worldwide differ, with some countries and/or regions within a country using TEOAEs and AABR and others using DPOAE screening as well. For example, screening protocols in India consist of three stages with TEOAE at the first and second stages of screening followed by AABR at

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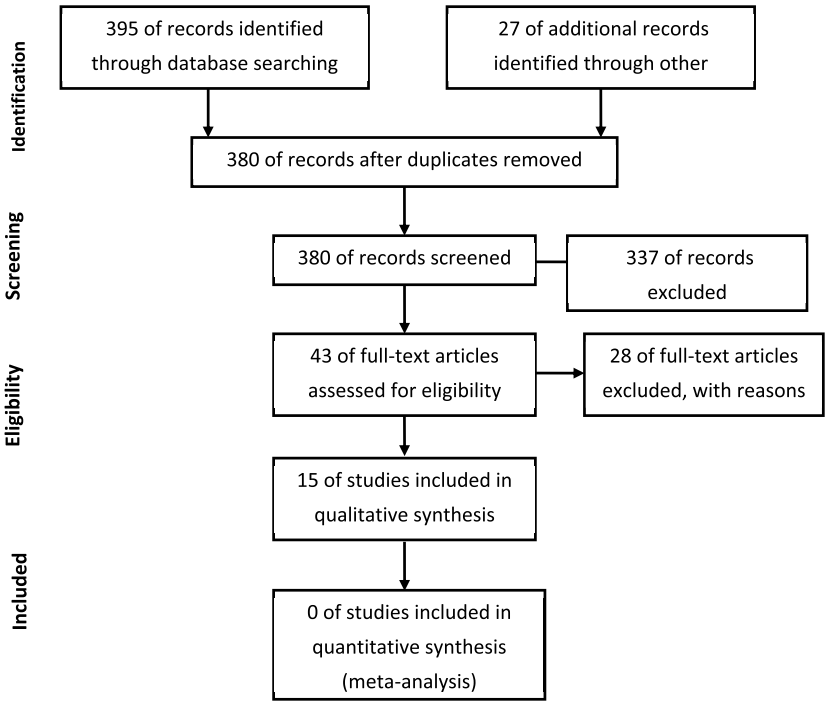

Fig. 1. The PRISMA flow diagram describing the study selection process.

the third stage. In comparison, hospitals in the United States employ a two stage screening protocol with TEOAE and AABR screening at both stages [6]. These differences in protocols should not confuse but rather guide stakeholders to develop relevant protocols in ensuring that the implemented NHS programmes attain certain benchmarks that support early identification and intervention for hearing loss [7].

There are many reasons why countries may choose to adopt one recommended protocol over another and this speaks to context and the constraints imposed within certain health care environments. Nevertheless, the ultimate choice at any given point in time should therefore extend beyond resource constraints and should consider current evidence from published literature when deciding on the screening measures. The Institute of Health Economics (2012) aimed at determining the accuracy of automated screening measures, and their influence on specific benchmark indicators such as detection rate of hearing loss and age at diagnosis. They concluded that the use of two-staged protocols using a combination of technologies was safe for newborns and that both OAEs and AABR were equally accurate measures within NHS programmes [8].

One of the ethical standards for NHS is that an appropriate, reliable, valid and safe test should be available and suitable to the target population being screened, for example, well babies versus high-risk infants [6]. In the United Kingdom, for example, well babies are reported to receive TEOAE screening followed by AABR if indicated by poor TEOAE results, whereas newborns requiring NICU care routinely receive both TEOAE and AABR screening [9]. This screening practice differs from some birthing facilities in the United States of America, where AABR is the common screening measure of choice followed by DPOAE and TEOAE. Notwithstanding these criteria, particularly that relating to sensitivity and specificity of measures may result in missed cases of hearing loss or an increased number of false positive findings. Ultimately, the choice of screening measures and the approach to screening should be guided by evidence from well-conducted pilot studies in each country [6,10]. These findings should facilitate the standardization of protocols within similar contexts. A low false-positive rate is essential in the success of a NHS programme and the reduction of false-positive results is therefore a key goal in developing a more reliable NHS programme [11]. Despite various protocols described in literature, one needs to carefully and systematically evaluate evidence from relevant studies that would assist in informing our choice in selecting evidence-based best measures that are suited for individual contexts. The current systematic review paper aimed at providing a review of the most current research in objective measures used within newborn hearing screening protocols with the aim of exploring the actual protocols in terms of the types of measures used and their frequency of use within a protocol, as well as their outcomes in terms of sensitivity, specificity, false positives, and false negatives worldwide.

2. Methods

A systematic review of peer reviewed published literature related to hearing screening measures used within NHS programmes worldwide from 2007 to 2016 was conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [12]. A number of electronic databases, namely, PubMed, Google Scholar and Science Direct were searched using the following key terms: newborn hearing screening, newborn hearing screening protocols, otoacoustic emissions, auditory brainstem response. Articles (with both qualitative and quantitative studies included) were chosen based on specific criteria. Firstly, the study had to have been published in English in peer reviewed scientific journals. Secondly, the article had to present original work related to NHS, of which one of the aims or aspects of the study needed to involve information related to the NHS protocol used and the outcome of this protocol in terms of false-positive rates, false-negative rates, sensitivity, specificity and/or referral rates. Thirdly, studies had to include at least one of these five test performance criteria. Lastly, articles were to report on studies conducted worldwide between 2007 and 2016, a time which was reflective of the time period post the Health Professions Council of South Africa (HPCSA) and Joint Committee on Infant Hearing (JCIH) early hearing detection and intervention (EHDI) position statements to the present time. Published articles related to the evaluation of specific screening equipment or software were excluded from the review. For reliability, two independent reviewers extracted specific information from the studies. Pertinent data and findings from the review were tabulated under the

Table 1
Comparison and Outcome of Various Screening Protocols Using Objective Measures within universal or well-baby newborn hearing screening programmes.

Country	Sample size	Objective Screening and/or Diagnostic Measures	Details of Screening Protocol	Results, Conclusion and/or Recommendations	Reference
Italy [25]	N = 8671	TEOAE, AABR and conventional ABR	Five Level screening protocol **First level:** TEOAE before discharge **Second Level:** Repeat TEOAE screening after two weeks for neonates who referred at the initial screening **Third level:** AABR at 45–90 days of life for newborns who *passed* first level but had risk factors and newborns who *referred* at the second level. **Fourth level:** Conventional ABR for infants who *referred* at the third level **Fifth Level:** Tympanometry, ABR and vocal audiometry for infants who did not *pass* the conventional ABR.	FP rates decreased with each step within the screening program. False positive rate was 0.03%. ABR plays a significant role in reducing the FP rates. Accuracy of NHS may be improved with the use of better screening protocols and conventional ABR is the most accurate measure when assessing function of the auditory system in NHS programmes.	[25]
Italy [26] [27]	N = 19 700 N = 146 026	TEOAE, diagnostic ABR	Two-stage TEOAE followed by diagnostic ABR for those newborns who *referred* with TEOAE and those at high risk for hearing loss Two-stage OAE for well-babies (the first being 48–72 h after birth and the second between 3 and 4 weeks of age if a *refer* result is obtained) followed by diagnostic ABR if a *refer* is obtained at the second screening. OAE screening prior to discharge for NICU infants followed by diagnostic ABR at 3–4 months of age if a *refer* result is obtained.	100% sensitivity and 99.3% specificity in detecting congenital hearing loss. A two-stage TEOAE followed by diagnostic ABR appears to be feasible, minimally invasive and accurate protocol. The screening protocol for NICU infants excluded AABR which resulted in delayed diagnosis of auditory neuropathy in some infants	[26] [27]
Nigeria [28]	N = 3333	TEOAE, AABR and diagnostic ABR	Two stage screening protocol followed by diagnostic ABR for all infants *referred* after the second stage screening in a hospital-based and community-based UNHS programme. **Stage 1:** TEOAE **Stage 2:** AABR for all infants who *referred* from Stage 1.	Referral rates from the first-stage TEOAE screening were higher (32.2%) than the recommended benchmark of 4% by the JCIH The introduction of AABR in the second stage reduced the referral rate Although the use of AABR in the first stage would have resulted in lower referral rates, it would have been impractical within the community-based screening.	[28]
Nigeria [16]	N = 1745	TEOAE, AABR	Two-stage screening protocol **Stage 1:** TEOAE **Stage 2:** AABR for newborns from the well-baby nursery that *referred* at the stage 1 screening and all newborns admitted to the special care baby unit.	High percentage of true-negative results (60.7%) followed by FP results (32.7%), TP (5.3%) and then FN (1.3%) results The FN and FP results were more evident in the newborns in well-infant nurseries, delivered vaginally or whose mothers received antenatal care. A careful evaluation of the trade-offs resulting from various TEAOE/AABR options needs to be investigated, and the effects on efficiency using a one-stage or two-stage screening protocol with the same technology needs to be carefully considered.	[16]
Brazil [29]	N = 200	TEOAE, AABR	Three different screening protocols **Protocol 1:** two-stage TEOAE **Protocol 2:** two-stage AABR **Protocol 3:** TEOAE followed by a retest with AABR for all newborns who *referred* with TEOAE.	Protocol 1 resulted in four times more the referral for audiological diagnosis in comparison to Protocol 2. The FP rate and specificity was better for Protocol 2, followed by Protocol 1 and lastly Protocol 3. Protocol 1: FP (2%), Specificity (98%) Protocol 2: FP (0.5%), Specificity (99.5%) Protocol 3: FP (6%), Specificity (94%)	[29]
Spain [30]	n = 2454 (TEOAE) n = 3117 (AABR)	TEOAE, AABR	Two different, two-stage screening protocols **Protocol 1:** two-stage TEOAE **Protocol 2:** two-stage AABR	A lower referral rate was obtained with AABR (2.6% and 0.32%), as opposed to TEOAE (10.2% and 2%). A lower FP rate was achieved with TEOAE during the first stage of screening as opposed to AABR, but a lower FP rate was achieved with AABR at the second stage of screening. A higher predictive value for hearing loss was achieved with a two-stage AABR protocol.	[30]
Spain [31]	N = 26 717	TEOAE only for screening ABR for diagnostic assessment	Two phases at different time periods **Phase 1:** TEOAE 48 h after birth **Phase 2:** TEOAE after 1 month for babies who obtained a *refer* result in phase 1 and after 2 months for babies who *passed* but presented with a risk factor for hearing loss Diagnostic assessment using ABR for babies who *refer* in the 2nd phase	Coverage rate was above 95% Referral rate for diagnostic assessment was low (3.8%)	[31]
Poland [32]	N = 351	TEOAE, DPOAE, ABR	**First stage:** Screening TEOAE **Second stage:** Diagnostic ABR and diagnostic DPOAE for neonates that	FP rate of 82.73% from the first stage- possibly attributed to having performed screening on the 2nd or 3rd day of life in the presence of amniotic fluid in the middle ear or debris in the external ear canal.	[32]

(*continued on next page*)

Table 1 (*continued*)

Country	Sample size	Objective Screening and/or Diagnostic Measures	Details of Screening Protocol	Results, Conclusion and/or Recommendations	Reference
			obtained a *refer* result in the first stage as well as for neonates with risk factors for hearing loss	The inclusion of AABR in the first stage may assist in improving quality of results and decreasing FP results.	
Taiwan [15]	N = 25 588	TEOAE, AABR	Three different screening protocols used at different time periods **Protocol 1:** One-stage TEAOE **Protocol 2:** TEOAE and AABR **Protocol 3:** One-stage AABR	Referral rates were lower for Protocol 3 as opposed to Protocol 1 & 2. No statistically significant difference was found with regard to the accurate identification rate of congenital hearing loss. The total cost was lower for Protocol 3 than Protocol 1 & 2. Intangible costs such as parental anxiety and transportation fees were lower for Protocol 3 due to a lower referral rate.	[15]
Sweden [2]	N = 31 092	TEOAE Diagnostic click-evoked ABR	Multiple TEOAE recordings (typically 3 sessions) **Stage 1:** TEOAE screening before discharge **Stage 2:** TEOAE screening as outpatient **Stage 3:** TEOAE screening if *refer* results were obtained **Stage 4:** Click-evoked ABR	TEOAE screening had high specificity and sensitivity was observed to be 100% The use of multiple TEOAE recordings reduced the referral for diagnostic ABR TEOAE was best recorded 3–6 days after birth.	[2]
Tapei City, China [33]	N = 15 790	AABR OAE Diagnostic ABR, ASSR	**Stage 1:** AABR screening at 24–26 h after birth **Stage 2:** AABR screening at 36–60 h of age or before discharge if *refer* results were obtained **Stage 3:** OAE and AABR at one month of age at a diagnostic hospital if a refer result was obtained on second screen Diagnostic ABR, ASSR and OAE (and behavioural observation audiometry or visual reinforcement audiometry) for infants who referred on Stage 3.	Coverage rate was 99.1% Referral rate was low (1%) revealing that a two-stage pre-discharge AABR screening strategy is effective	[33]
Beijing, China [13]	N = 1062	TEOAE, AABR	**Stage 1:** TEOAE screening, followed by AABR if a refer was obtained for TEOAE (sequential screening) **Stage 2:** TEOAE screening six weeks after birth if refer result on first TEOAE screening **Stage 3:** Diagnostic ABR if refer on TEOAE rescreen	Referral rate was lower (3%) for TEOAE/AABR sequential screening in comparison to TEOAE screening (11%) False positive rates decreased with the inclusion of AABR	[13]
Israel [34]	N = 5212	TEOAE AABR	**Stage 1:** TEAOE screening followed by a repeat TEOAE screening a day later if a *refer* result was obtained (well-babies) TEOAE and AABR for neonates with risk factors **Stage 2:** AABR screening if a *refer* result was obtained after the second TEOAE screen Comprehensive audiological assessment following a *refer* result from stage 2. Audiological measures were not specified.	Coverage rate was 94.5% Referral rate of 5.18%	[34]
South Africa [35]	N = 7452 n = 3573 (DPOAE) n = 3879 (AABR)	DPOAE, AABR	**Protocol 1:** Three-stage DPOAE followed by diagnostic AABR if a refer result was obtained at the third screen **Protocol 2:** Three-stage AABR followed by diagnostic AABR if a refer result was obtained at the third screen	Referral rate was significantly lower for AABR than for DPOAE	[35]

Pass: result indicating no requirement for further assessment.
Refer: result indicating the need for further assessment.

following headings: country where the study was conducted; objective screening and/or diagnostic measures employed; details of the NHS protocol investigated; results found, conclusion and/or recommendations made; and the reference/citation.

Based on the number of studies, and also because this was a systematic review paper, no meta-analysis or sensitivity analysis was performed. In this paper, selected studies were compared and summarized on the basis of existing evidence and theories. Current results are therefore based on a qualitative rather than a quantitative analysis of the studies reviewed.

3. Results and discussion

Four hundred and twenty two articles were retrieved from the initial search. Of these, 395 were identified from the databases and 27 from manual reviews of the reference lists from the identified publications. Fifteen records were excluded due to duplication. A further 337 records were removed post abstract and title review. Ultimately, 43 full text articles were screened for eligibility, of which only 15 were original articles that met the study specifications. Fig. 1 represents the PRISMA flow diagram which describes the process of study selection.

Findings from the 15 articles reviewed are tabulated in Table 1. Thirteen studies were related to universal newborn hearing screening (screening of all newborns), and two were related to the screening of healthy newborns only [13–15]. Two of the studies indicated the use of DPOAEs, AABR and/or diagnostic ABR within protocols while the remaining 13 indicated the use of TEOAEs. Of these remaining 13 studies, nine utilized TEOAEs within a UNHS programme, and two involved screening of healthy newborns only.

It is evident from published literature that there is no uniformity in screening measures used. Nonetheless, many of the NHS programmes, whether universal or involving healthy newborns utilise TEOAEs. There were only two programmes that documented the inclusion of DPOAEs in their protocol. TEOAEs have been more commonly explored within a screening protocol, either as a single screening measure, or in combination with AABR. TEOAEs have however been reported to be the most common screening measure in NHS programmes worldwide as they are easier to conduct, have a shorter test time and are considered less expensive in terms of the need for consumables [16]. Repeated use of TEOAEs within a multi-stage screening protocol has also been reported to aid in reducing the number of more expensive, secondary level evaluations [2,17,18]. Berninger and Westling [2] also found that the specificity of TEOAE measurements increased with repeated TEOAE screening.

In addition to the use of TEOAEs, nine of the studies included the use of AABR, two of which involved screening of healthy newborns only. The TEOAE/AABR combination has been commonly employed for the screening of NICU infants in developed contexts [6]. Although TEOAEs can be conducted within a shorter test time in comparison to AABR, it is argued that they cannot completely replace AABR and need to be carefully considered within a two-stage protocol [19,20].

Four of the articles reviewed compared different screening protocols whereas the remaining 11 articles reported on existing two, three or even four stage protocols (Table 1). Of the studies with a two or more staged protocol, almost all began with the use of TEOAEs screening except for the NHS programme in Tapei City, China where AABR was used at the initial hearing screening. Overall, findings indicated that the inclusion of AABR or diagnostic ABR facilitated the decrease in false-positive (FP) rates, as well as the referral rates (Table 1). The use of both OAE and AABR has been argued by a number of authors [5,21] as the use of OAEs in isolation may miss the proportion of babies with conditions such as auditory neuropathy or auditory dysfunction.

Whilst the above mentioned studies reflected in Table 1 have been conducted within a universal NHS programme, investigations regarding various screening protocols have also more specifically been conducted in targeted populations (either neonates from a well-infant nursery or high-risk neonates). Suppiej et al. [22] investigated the use of TEOAE, AABR and ABR (using click stimuli) in neonates with high-risk factors for hearing loss. Results from this study indicated that although TEOAEs and ABRs were able to predict hearing loss in high risk neonates admitted to the NICU, ABR was the most reliable test as it had the best sensitivity and specificity with AABR being the worst. Similar findings were reported by Martines and colleagues who concluded that a TEOAE/ABR combination is the gold standard for screening NICU babies who are at risk for auditory neuropathy [23]. Berg, Prieve, Serpanos and Wheaton [24] compared the use of two screening protocols (AABR followed by OAE when *refer* results were obtained from AABR, and OAE followed by AABR when *refer* results were obtained from OAE) in infants admitted to the well-infant nursery. Results from this study indicated that the conventional protocol of OAE followed by AABR (if a *refer* OAE result was obtained) was more efficient in terms of time. The authors further concluded that the use of OAEs as a screening tool for infants in well-baby nurseries is reasonable.

The choice of screening protocol employed within a NHS programme whether universal or risk-based, is influenced by a variety of factors such as costs, logistics, infrastructural considerations, targeted referral rates and follow-up default rates [16]. Although the same screening measures may be employed, there are clear differences in their implementation or use within a screening protocol. Differences in screening protocols highlight that the choice of screening protocol may not only be determined by what is feasible within a particular context, but also by the objective of achieving the ideal screening protocol (achieving good sensitivity and specificity, achieving a high initial *pass* rate or achieving a low-cost protocol). This is particularly important for contexts where the above-mentioned influencing factors may significantly impact on the success of a NHS programme. This is also important as ethical clinical practice is paramount.

4. Conclusions and recommendations

Generally, findings in this review revealed firstly, that there is lack of uniformity in protocols adopted within NHS. Secondly, many of the NHS protocols reviewed consist of two or more tiers or stages, with transient evoked otoacoustic emissions (TEOAEs) and automated auditory brainstem response (AABR) being most commonly used. Thirdly, DPOAEs appear to be less commonly used when compared to TEOAEs. Lastly, a question around routine inclusion of AABR as part of the NHS protocol remains inconclusively answered.

The current review indicated that there is sufficient evidence to suggest that the inclusion of AABR within a NHS programme is effective in achieving better hearing screening outcomes. The use of AABR in combination with OAEs within a test-battery approach or cross-check principle to screening is appropriate, but the inclusion of AABR to facilitate appropriate referral for diagnostic assessment needs to be systematically studied. The use of a two-stage or multiple stage protocol contributes toward decreased referral rates. Increased accuracy in screening, with enhanced internal quality assurance as offered is important in contexts where there is increased risk of hearing loss but limited resources.

Conflicts of interest

The authors declare no conflicts of interest.

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